# enicotine TECHNOLOGY

Taking the Smoke Out of Smoking

**Tobacco Products Scientific Advisory Committee Presentation**
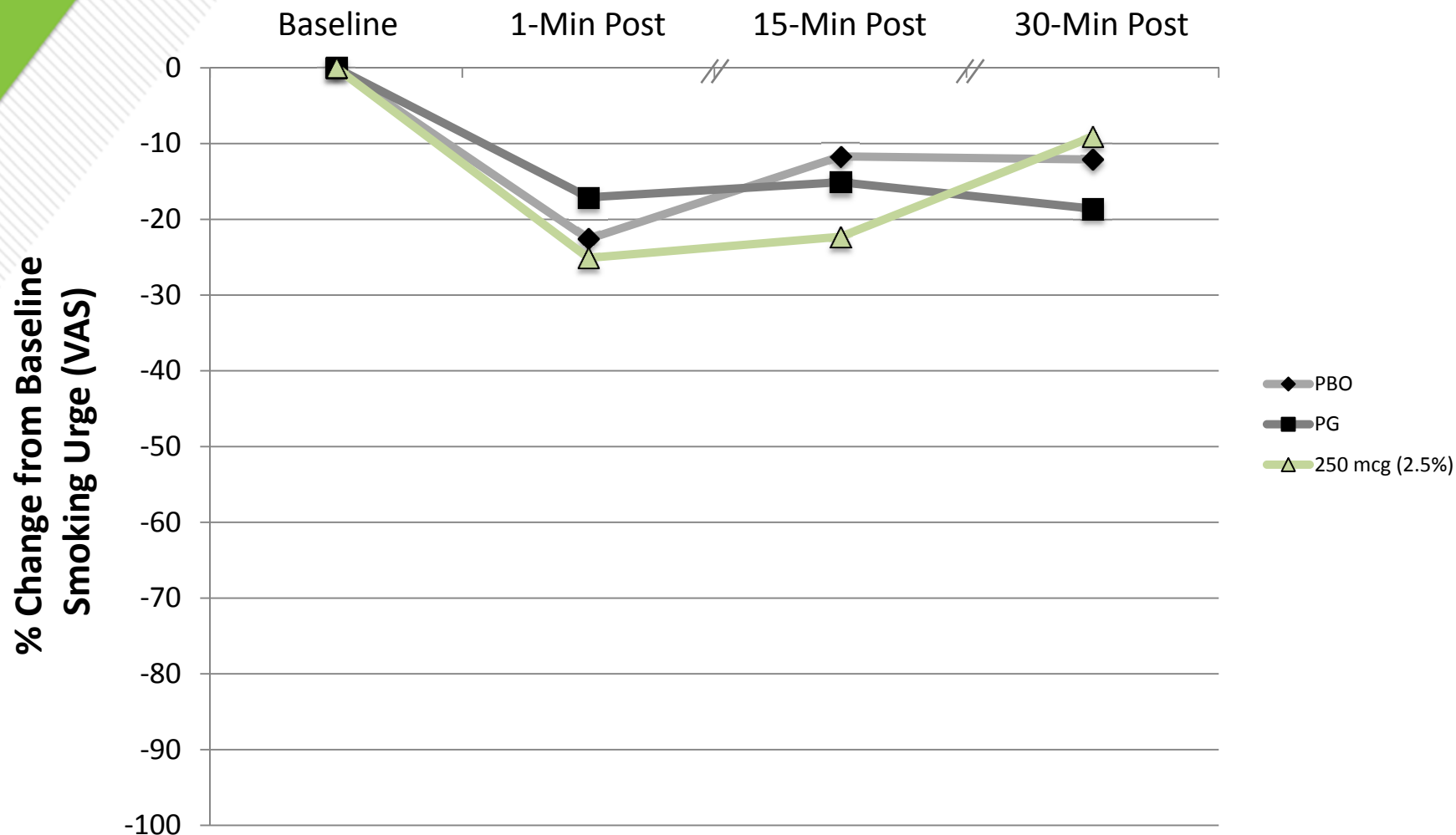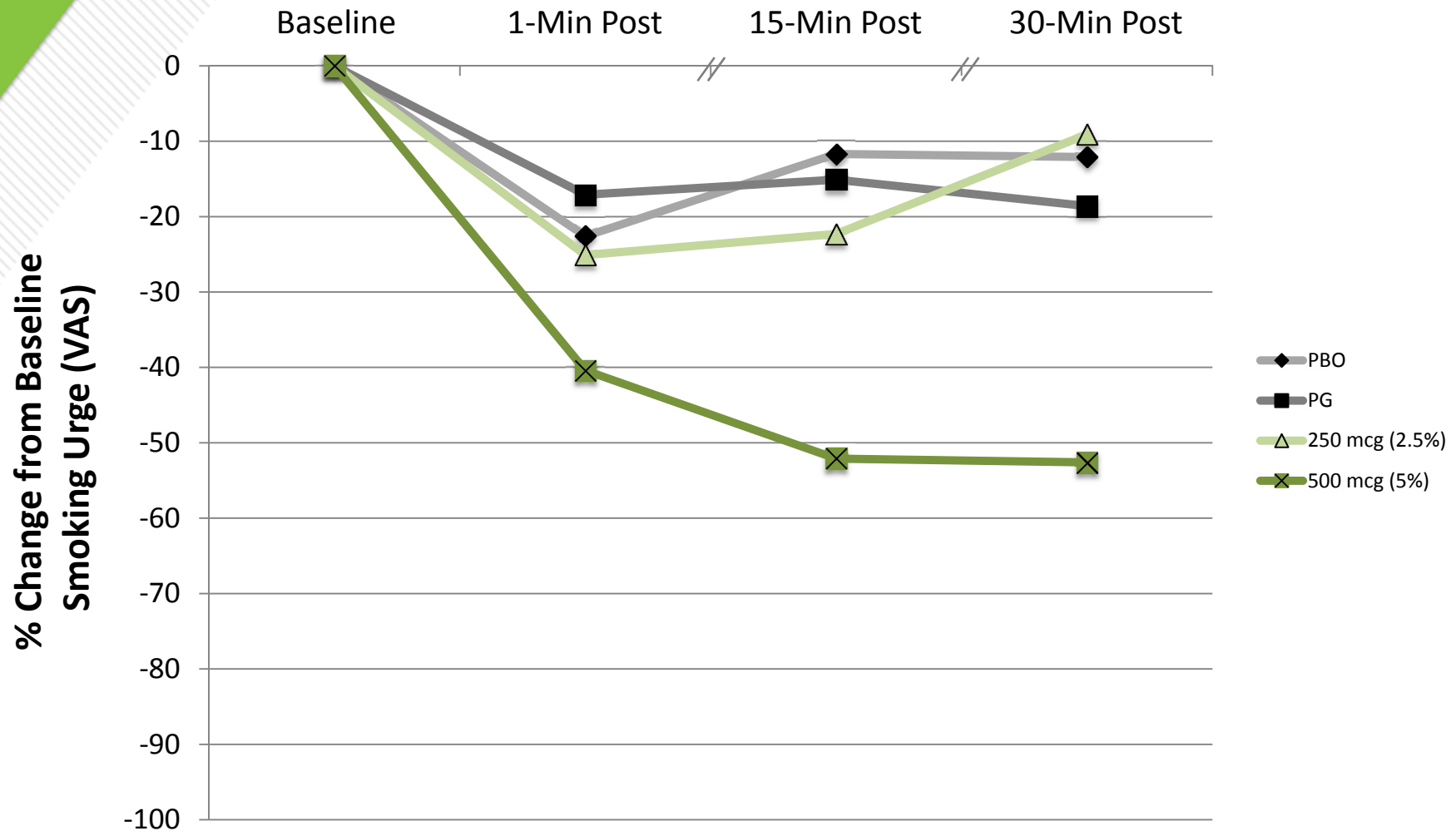**April 16th, 2014**

# Overview

- Innovation in ENDDs can:
  - Effectively reduce smoking urges
  - Reduce nicotine exposure vs. cigarettes
  - Reduce exposure to harmful and potentially harmful constituents
  - Reduce similarity to smoking behavior
  - Track usage and dependence while also guiding users toward goals using eHealth tools
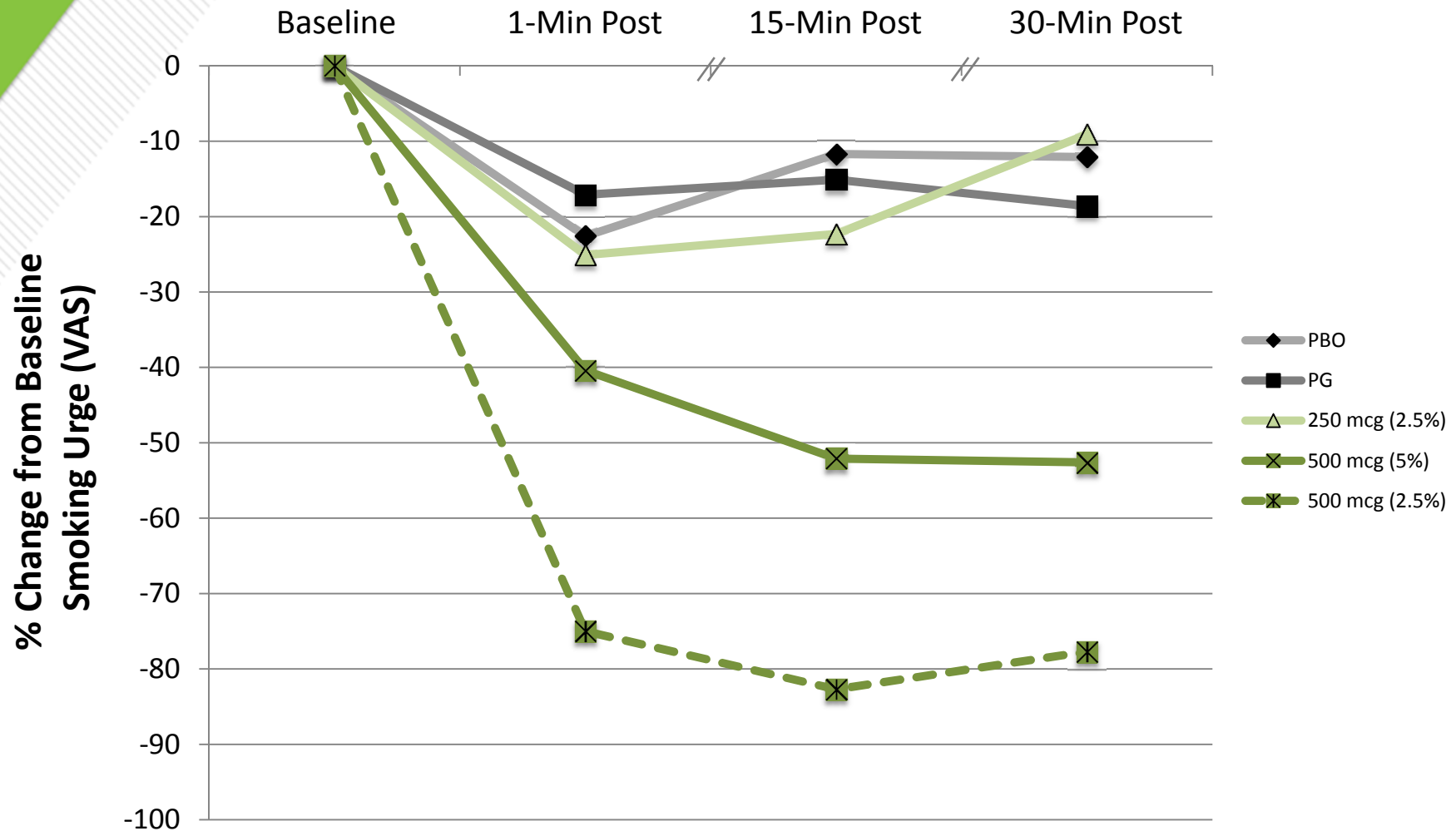
# VAS Smoking Urge: % Change from Baseline[*]



* Hufford et al. (2014) SRNT

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*Chart showing % Change from Baseline Smoking Urge (VAS) across Baseline, 1-Min Post, 15-Min Post, and 30-Min Post timepoints. Legend: PBO, PG, 250 mcg (2.5%), 500 mcg (5%), 500 mcg (2.5%).*
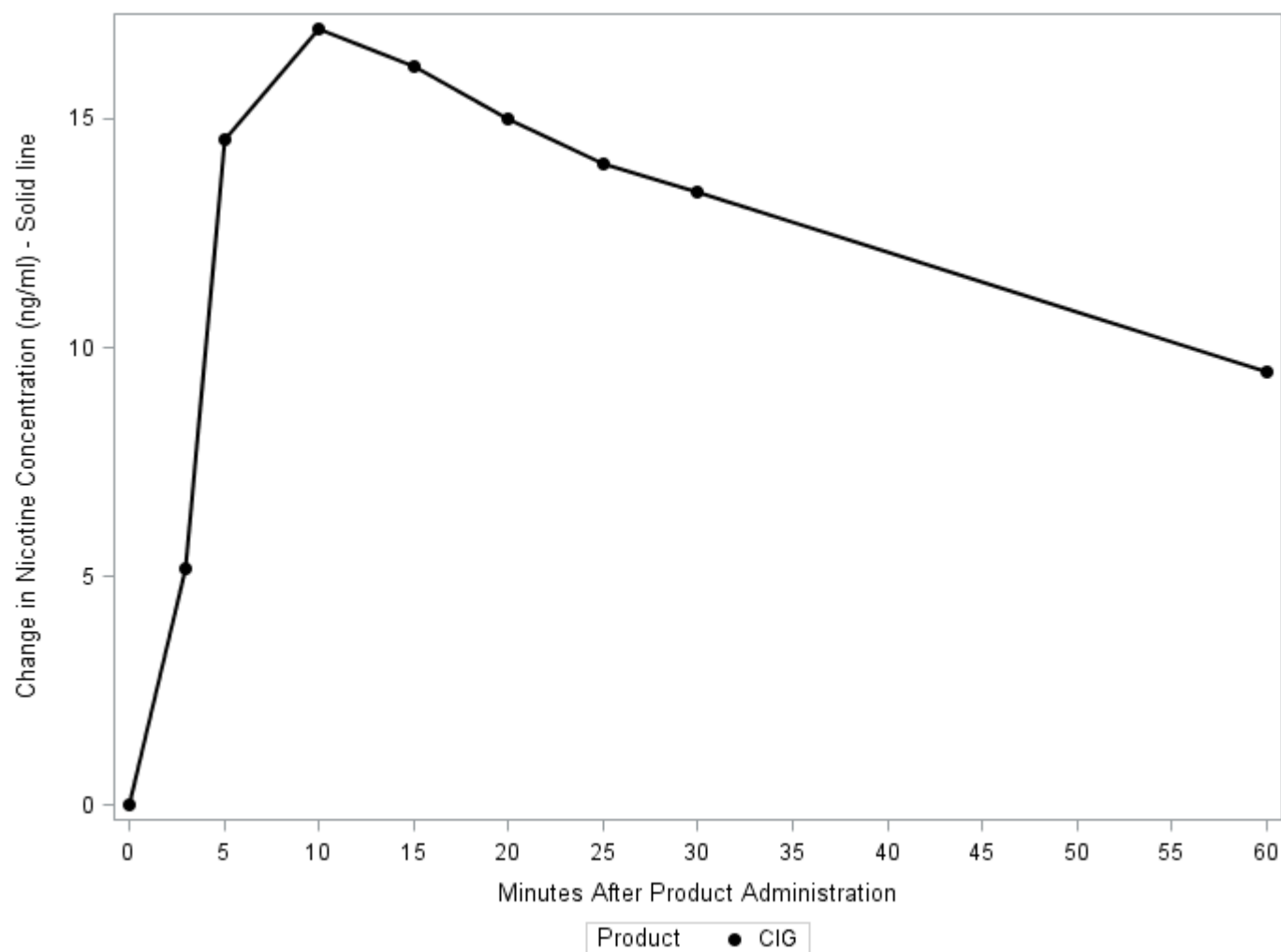
* Hufford et al. (2014) SRNT
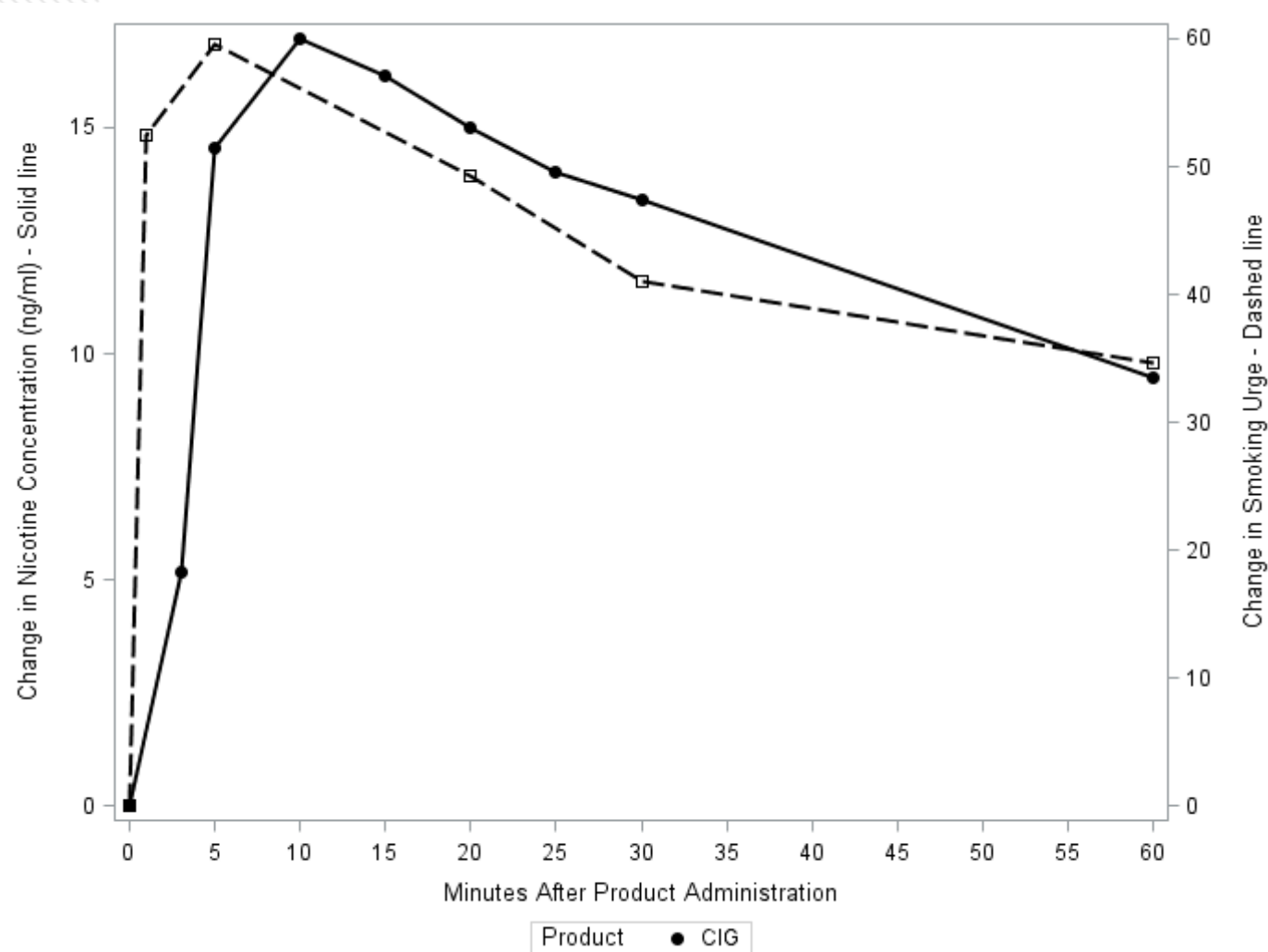
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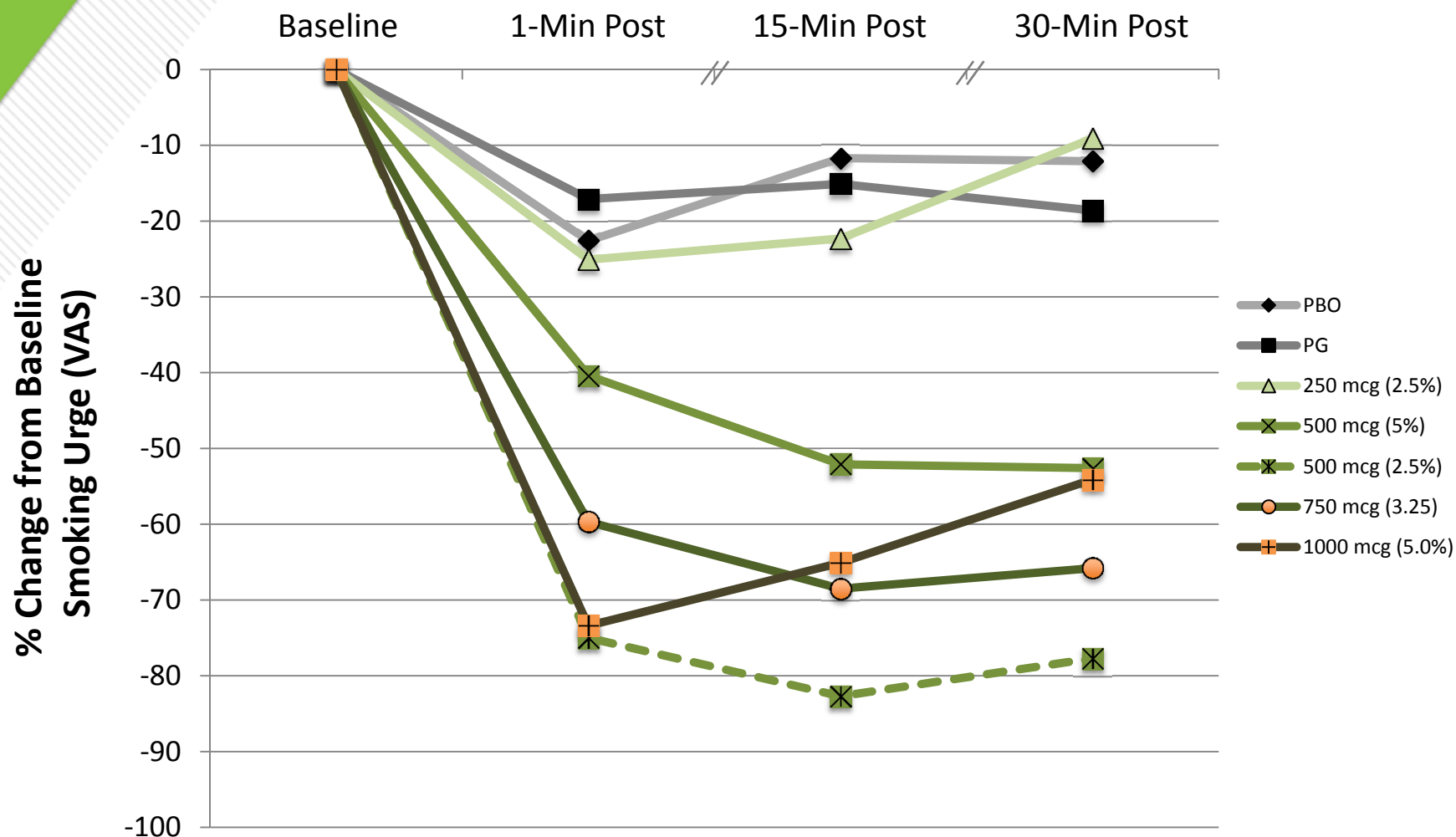


* Hufford et al. (2014) SRNT

# Efficient Use of Nicotine*



* Unpublished data

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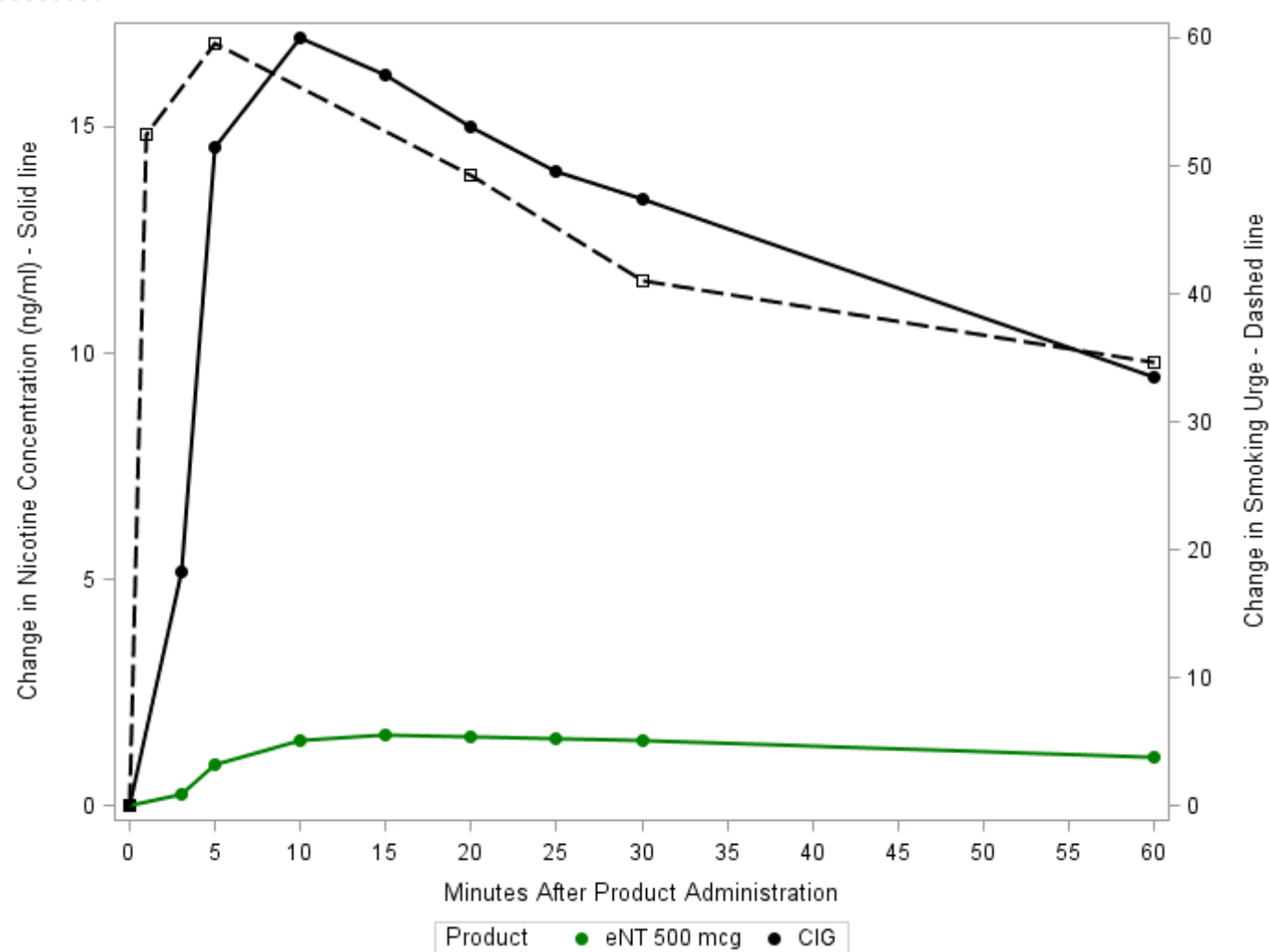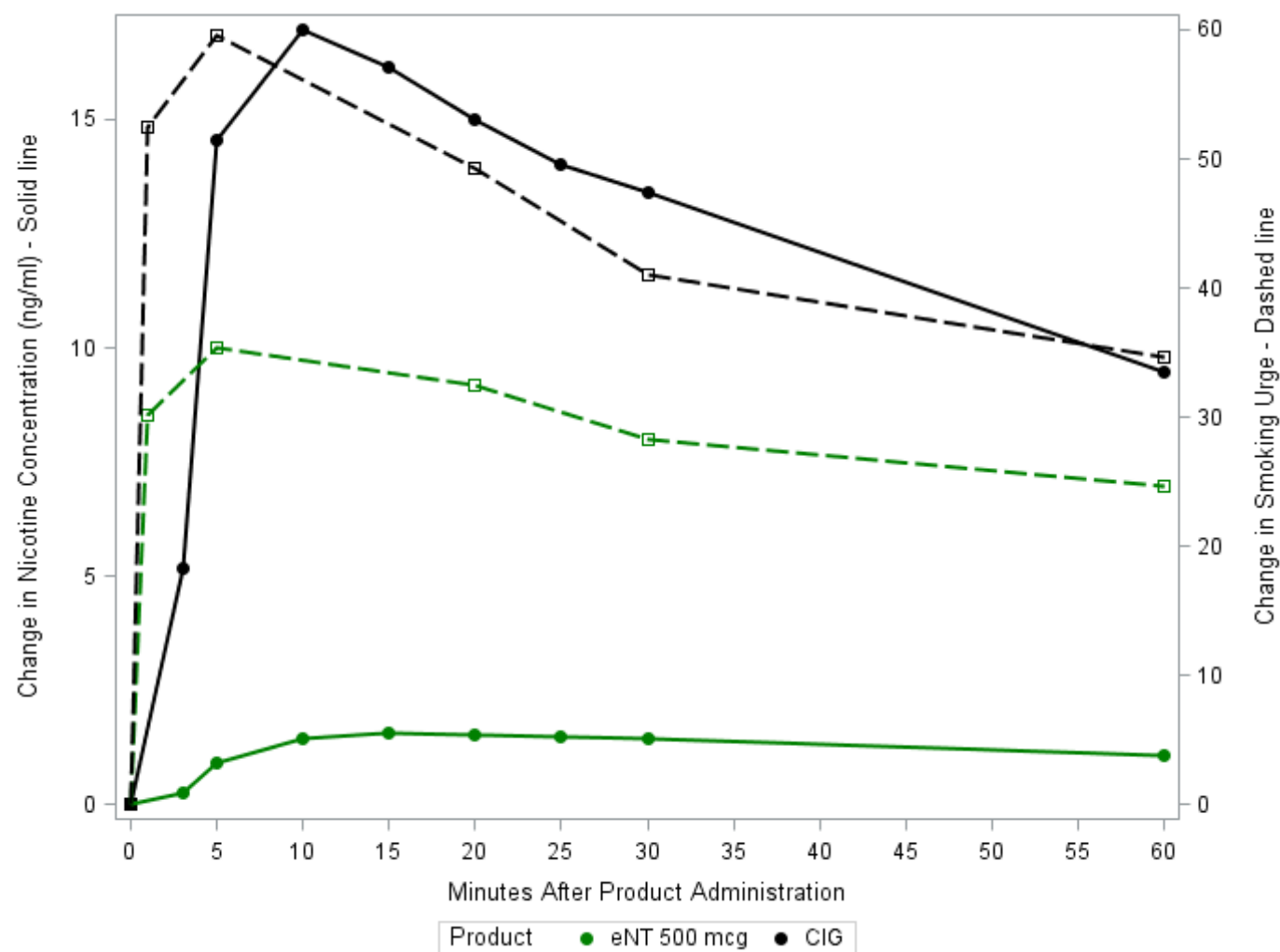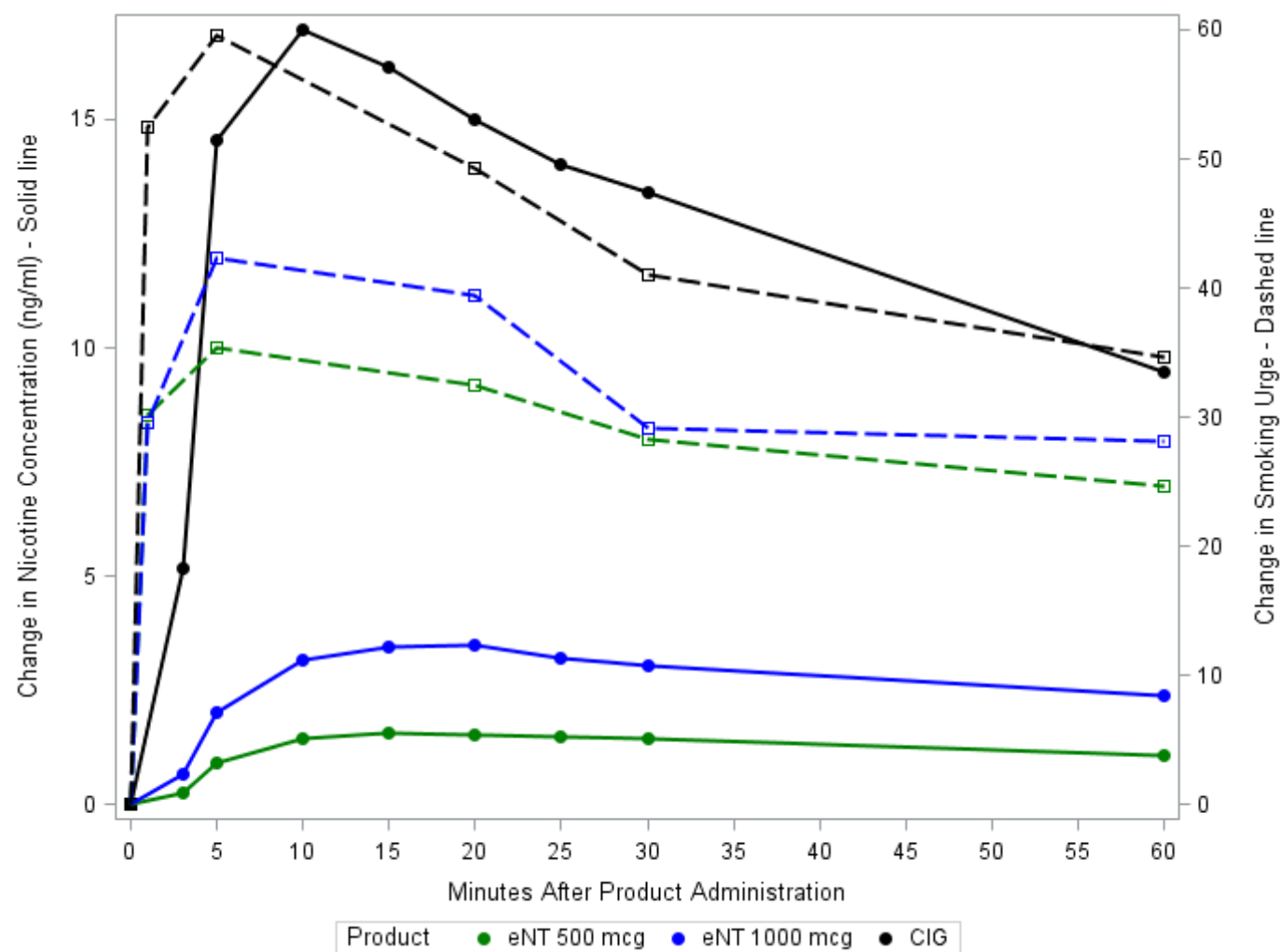
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# High PK Not Required to Activate Vast Majority of α4β2 Receptors



Figure 3. 2-[¹⁸F]fluoro-3-{(S)-azetidinylmethoxy}pyridine (2-F-A-85380) positron emission tomography (PET) images before (top row) and 3.1 hours after (bottom row) cigarette smoking. Images were obtained by averaging the six 10-minute frames over the 1 hour prior to the smoking break and by averaging the seven 10-minute scans from a mean of 3.1 hours after smoking the cigarette amount listed. The far right column shows a magnetic resonance image (MRI) of the brain and a PET image of nondisplaceable radioactivity distribution (calculated). All PET images were aligned to the level shown on the MRI.

* Brody et al., Cigarette Smoking Saturates Brain a4B2 Nicotinic Acetylcholine Receptors; *Arch Gen Psychiatry. 2006;63:907-915*

**Estimating the Harms of Nicotine-Containing Products Using the MCDA Approach**

David J. Nutt[a]  Lawrence D. Phillips[b]  David Balfour[f]  H. Valerie Curran[c]
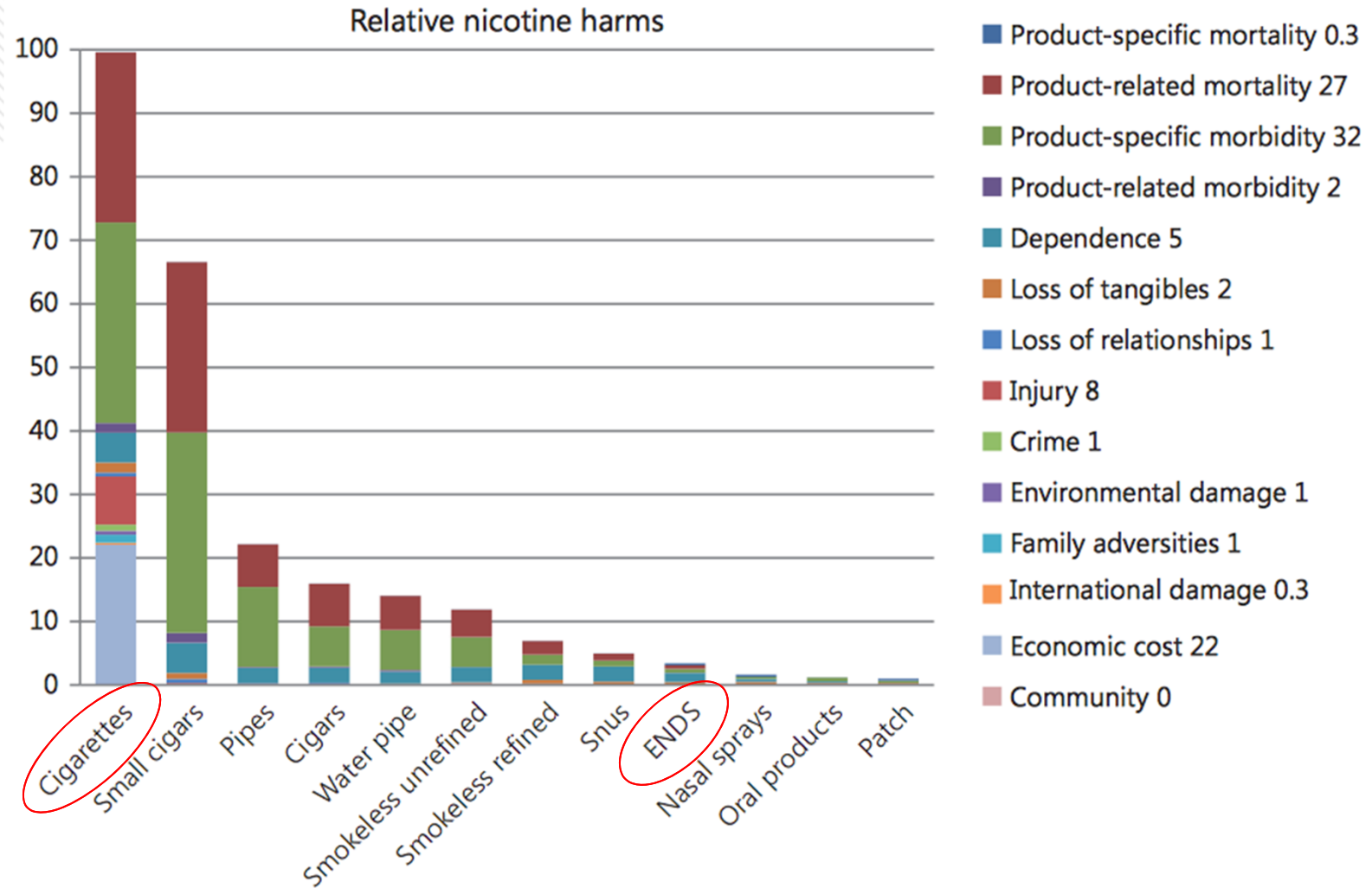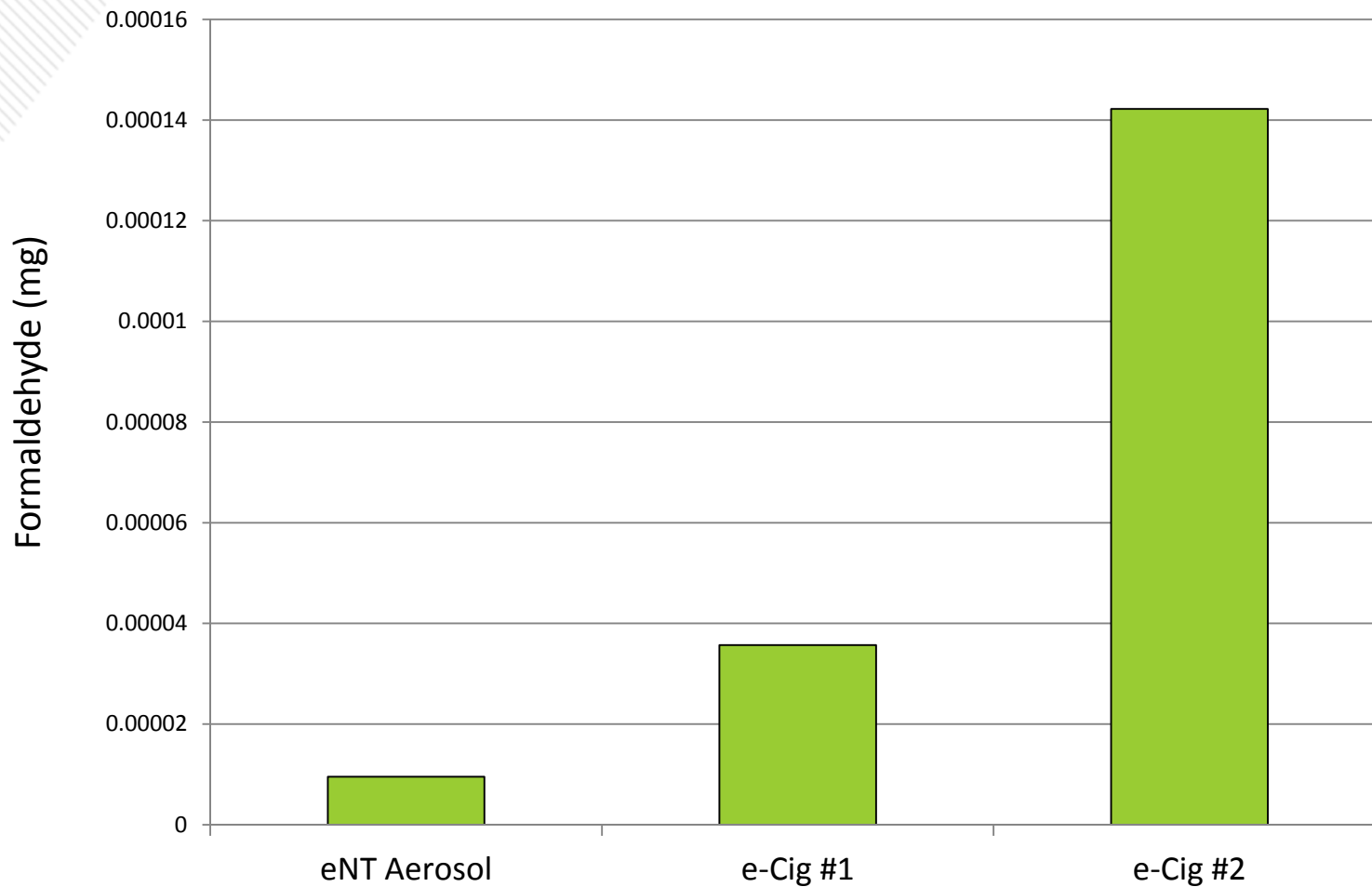Martin Dockrell[d]  Jonathan Foulds[h]  Karl Fagerstrom[i]  Kgosi Letlape[k]
Anders Milton[j]  Riccardo Polosa[l]  John Ramsey[e]  David Sweanor[g]

# Relative Harms

**Relative nicotine harms**

Legend:
- Product-specific mortality 0.3
- Product-related mortality 27
- Product-specific morbidity 32
- Product-related morbidity 2
- Dependence 5
- Loss of tangibles 2
- Loss of relationships 1
- Injury 8
- Crime 1
- Environmental damage 1
- Family adversities 1
- International damage 0.3
- Economic cost 22
- Community 0

Categories (x-axis): Cigarettes, Small cigars, Pipes, Cigars, Water pipe, Smokeless unrefined, Smokeless refined, Snus, ENDS, Nasal sprays, Oral products, Patch

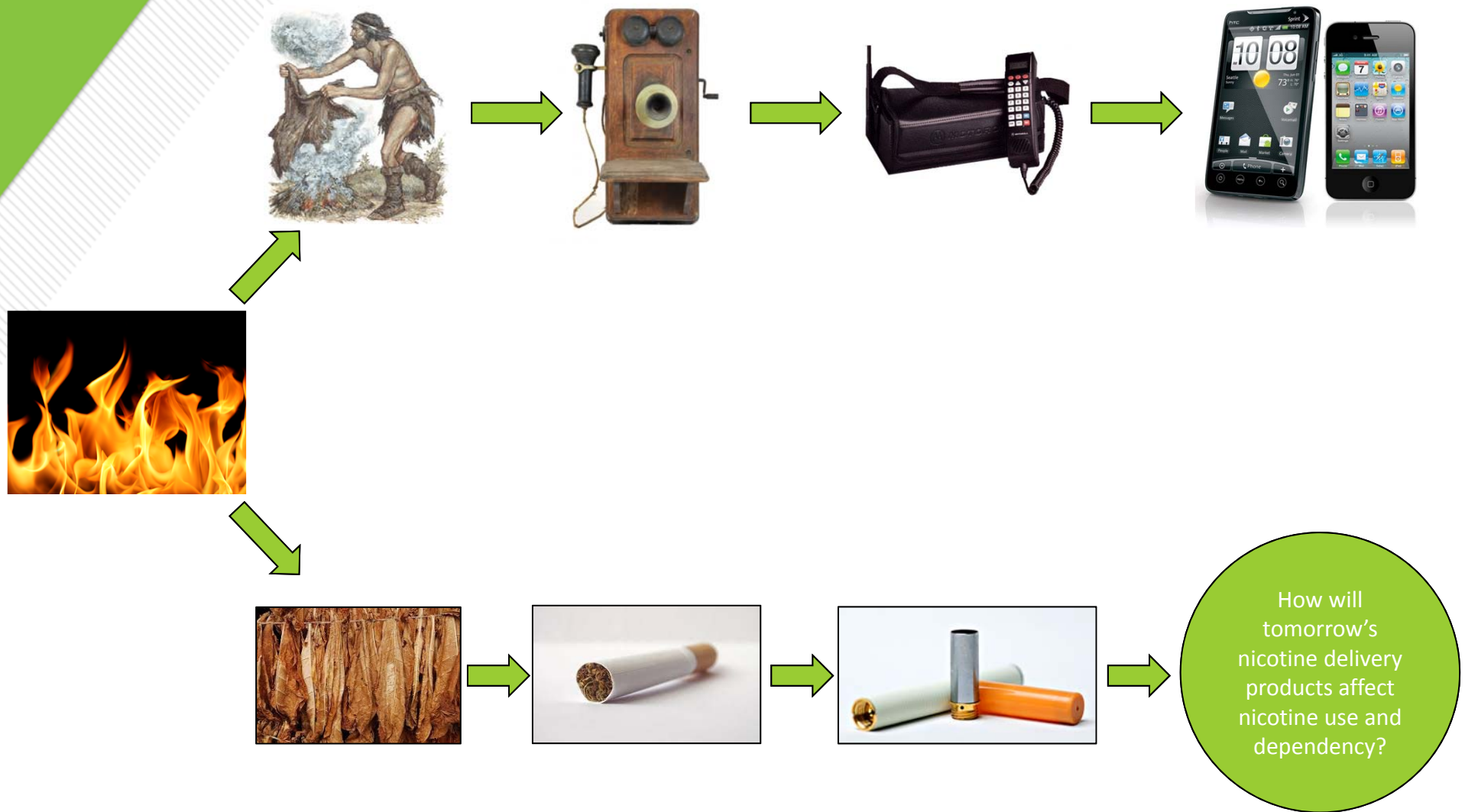# Possible to Reduce Formaldehyde Per Inhalation



* Unpublished data

# Innovation's March Forward...



How will tomorrow's nicotine delivery products affect nicotine use and dependency?

# Evolution in Form Factor & Nicotine Delivery

## TODAY



✓ Look like cigarettes
✓ Glow like cigarettes
✓ Have second-hand vapor
✓ Inconsistent nicotine delivery

# Evolution in Form Factor & Nicotine Delivery

TODAY ⟶ TOMORROW





✓ Look like cigarettes
✓ Glow like cigarettes
✓ Have second-hand vapor
✓ Inconsistent nicotine delivery

✓ May not resemble cigarettes
✓ May not glow like cigarettes
✓ Have <u>no</u> second-hand vapor
✓ Consistent nicotine delivery

# Real World Use:
# Passive vs. Purposeful

TODAY



✓ Use take place in a complete vacuum
✓ No leveraging of mobile technology
✓ No leveraging of eHealth tools
✓ Academic research only using Ecological
  Momentary Assessment (EMA)

# Real World Use:
## Passive vs. Purposeful

TODAY ⟶ TOMORROW



✓ Use take place in a complete vacuum
✓ No leveraging of mobile technology
✓ No leveraging of eHealth tools
✓ Academic research only using Ecological Momentary Assessment (EMA)

✓ Bluetooth enabled devices track usage
✓ eHealth tools guide users to goals
  ✓ Transition from combustibles
  ✓ Tapering to quit nicotine entirely

# Summary

New products "should be somewhat more reinforcing than nicotine replacement therapies but perhaps less reinforcing than conventional cigarettes... Ideally, [such a device] would be sufficiently reinforcing so as to attract smokers away from conventional cigarettes but not enough to encourage the widespread dependent use of the product by individuals who were previously non-users, or who would have quit smoking."

-- IOM's *Scientific Standards for Studies on Modified Risk Tobacco Products*, 2012, p.7)